

REMARKS

In response to the Office Action mailed on September 15, 2010, Applicant submits this Amendment and the Request for Continued Examination (RCE) filed concurrently herewith.

In the Office Action, the Examiner rejected claims 60-62, 64, 66, 67, 83, 84, 87 and 88 under 35 U.S.C. § 102(b) as allegedly being anticipated by Melvin (U.S. Patent No. 5,957,977) and rejected claims 68 and 85-90 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Melvin. The Examiner made the rejections final.

By this Amendment, Applicant amends claims 83, 85, 87, and 88, and cancels claims 89-90 without prejudice or disclaimer. Claims 60-62, 64, 66-68, and 83-88 are currently pending. Of these claims, claims 83, 85, and 87 are independent.

Applicant respectfully traverses the rejections of claims 60-62, 64, 66-68, and 83-90 over Melvin.

Independent claims 83, 85, and 87 are each drawn to a method of treating an in situ mitral valve. Each of claims 83, 85, and 87 requires, among other things, "securing a device" to an in situ mitral valve. The device includes a ring-like member (claim 83) or ring (claims 85 and 87) and a plurality of flexible elongate members. Each of claims 83, 85, and 87 further requires method steps involving first and second anchoring structures, wherein "the second anchoring structure is discrete from the first anchoring structure."

Melvin discloses an activator device for actively compressing one or more chambers of a natural heart to assist with blood circulation. As shown in Fig. 2, the disclosed mechanical activator device 50 includes an internal stint 52 and an external

yoke 70 for placement around a portion of the exterior surface of the heart. See col. 3, ll. 3-11. The internal stint 52 includes a septal splint 54, a first ring 56, and a second ring 58. In addition, the external yoke 70 may be fixed to a portion of the internal stint 52 by a number of transmural cords 86.

“The generally stirrup shaped yoke 70 restricts free motion of the natural heart 10 so that the natural heart 10 can be *activated*.” Col. 5, ll. 35-37 (emphasis added). The yoke includes a gel-filled cushion portion 80 and an activator 74. The activator 74 includes a hydraulic arm 75 and a plurality of bands 84 extending therefrom. “In fluid communication with the arm 75 via a driveline 92 is a pump unit “P”, such as a pneumatic or a hydraulic pump for controlling or altering the fluid volume within arm 75.” Col. 6, ll. 38-41. As clearly shown in Figs. 2 and 6, each of cords 86 that extends from either of rings 56 & 58 extends to yoke 70. Indeed, as explicitly taught by Melvin, each of cords 86 “is passed through a hole in the margin of yoke 70, through cardiac tissue, and preferably the ventricular wall, and through the internal stint 52.” Col. 8, ll. 34-37.

In use, pump “P” increases the pressure within arm 75 so that the shape of arm 75 is altered to an activated condition. In particular, the activator 74 deforms cardiac tissue by moving arm 75 from a relaxed condition (e.g., Fig. 7A) to an activated condition (e.g., Fig. 7B). As the activator 74 presses against the external surface of the heart, the volume of at least one chamber of the heart is decreased so that blood is pumped out of that chamber and into the circulatory system. Following activation, the activator 74 and arm 75 return to the relaxed condition and release from against the external surface of the heart. The combination of the stint 52 and yoke 70 assist in returning the volume of the chamber to an uncompressed condition, so that the

chamber may refill with blood. This procedure is then repeated. See, for example, col. 3, ll. 33-44. In this way, the disclosed Melvin device activates or “pumps” a heart.

Melvin, however, fails to disclose, teach, or otherwise suggest first and second anchoring structures disposed at the distal portions (claim 83) or ends (claims 85 and 87) of the claimed first and second flexible elongate members, wherein “the second anchoring structure is discrete from the first anchoring structure,” as required by independent claims 83, 85, and 87. In the Office Action, the Examiner alleges that the Melvin cords 86 correspond to the claimed elongate members. See, for example, Office Action at pages 2-3. Applicant respectfully disagrees. Even if cords 86 may be construed to correspond to the claimed elongate members, cords 86 and the Melvin device fail to meet the other recitations of independent claims 83, 85, and 87 for at least the following reason.

As shown in Figure 2, the distal ends of each of cords 86 are secured to portions of yoke 70. Thus, even if one or more of those portions of yoke 70 may be arbitrarily construed to correspond to the claimed first and second anchoring structures, those portions are not discrete from one another. In fact, as shown in Figs. 2, 4, and 5A-5B, all portions of yoke 70 are connected to one another, such that the yoke 70 forms a continuous loop. Thus, Melvin fails to disclose first and second anchoring structures disposed at distal portions or ends of the claimed first and second anchoring structures, respectively, wherein “the second anchoring structure is discrete from the first anchoring structure.” Accordingly, Melvin fails to disclose, teach, or otherwise suggest each and every limitation of independent claims 83, 85, and 87.

For at least these reasons, Applicant respectfully requests reconsideration and withdrawal of the rejections of claims 60-62, 64, 66-68, and 83-90 over Melvin.

Should the Examiner wish to discuss this Amendment, or have any questions or concerns, he is invited to telephone the undersigned at (202) 408-4221.

The Office Action contains characterizations of the claims and the related art with which Applicant does not necessarily agree. Unless expressly noted otherwise, Applicant declines to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and/or drawings in this Amendment, it is to be understood that Applicant is in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification, abstract, and/or shown in the drawings. Rather, Applicant is entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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By: 

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